April 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

National
COMMUNITY
PHARMACISTS
Association

*Formerly NARD, the National Association of Retail Druggists*

**Subject: Status of Useful Written Prescription Drug Information for Patients; Docket No. 00N-0352, 65 Fed. Reg. 7022 (February 11, 200)**

To Whom it May Concern:

The National Community Pharmacists Association (NCPA) is pleased to submit comments to the FDA regarding the methodology that will be used to assess the quantity and quality of written information accompanying prescription medications provided to patients.

The National Community Pharmacists Association, formerly NARD (the National Association of Retail Druggists), represents the pharmacist owners, managers, and employees of nearly 25,000 independent community pharmacies and 60,000 pharmacists across the country. Independent pharmacists, independent pharmacy franchises, and independent chains dispense nearly one-half of the nation's retail prescription drugs.

NCPA supports the voluntary provision of useful written information to patients. For over a century, patients have turned to independent community pharmacists to provide information about their medications. In more recent years, the patient leaflets that may be generated by pharmacy computer systems have provided an excellent tool for pharmacists to use in supplying written information to patients. However, it should be kept in mind that written information, though valuable, is somewhat one dimensional in the scope of information it can provide to patients. Patient access to face to face oral communication with their physician and pharmacist, as mentioned in Secretary Shalala's January 13, 1997 letter to Keystone Center Executive Vice President John Ehrmann (see attached), is imperative to ensure that patients safely and effectively maximize the benefits of their medication therapy.

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NCPA opposed and continues to oppose regulation of the distribution of written information. We supported and continue to support private sector initiatives to increase the quality and quantity of written patient information and believe that the interim assessment of community pharmacies showing that pharmacies are providing information to 87% of patients demonstrates emphatically the commitment of community pharmacy in meeting the goals of the Keystone plan.

00N-0352

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**Minimum Threshold for Useful Written Prescription Information:** The term "useful" is a highly subjective term and may be interpreted in a variety of ways. Attempts to define useful may be an elusive task, however, one essential element in the determination of what is useful is measuring the patient's acceptance of the information piece and their ability to use the information to augment oral information from their physician and pharmacist. Therefore, NCPA contends that it is imperative that a range of consumers from varying backgrounds be consulted to determine what is useful in the marketplace for consumers.

**Weighing of Criteria**: Attempting to place more weight on some criteria than others would be extremely difficult due to variance in drug properties. Thousands of prescription medications are available in the marketplace—each with their own unique chemical properties and side effects. Attempting to weight criteria for each of these drugs equally is a "one size fits all" approach that would not be appropriate. Furthermore, the subjective nature of what criteria patients value most make categorizing all criteria by the same scale a moving target. As an example, a patient who takes the drug warfarin for a chronic condition might be much more interested in contraindications because of the many drug interactions associated with that drug then they are concerned with the benefits of the drug which, in this example, they are most likely already aware of having used the drug for a substantial amount of time. It would be nearly impossible to customize written information for every patient's condition and their perception of which criteria are most important.

**Types of Information:** The FDA is requesting comments on whether or not additional criteria and/or additional information should be added to the assessment process. NCPA believes that it is important that the patient information is informative but also consumer friendly. Thus, we believe that information should be limited to one page. Adding additional pages is prone to reduce the likelihood of patients reading the material. Patients must be motivated to read the information they are given. Again, NCPA strongly believes that a large number of consumers from diverse background should be asked what information they find useful. Until it is determined what written information patients would like to receive and what information motivates them to positively effect their medication therapy, establishing criteria is an exercise in speculation.

**Role of Consumers and Others in Assessing Usefulness**: As stated above, including a wide range of consumers from diverse backgrounds is essential to assess the usefulness of patient information. Representatives from pharmacy, pharmacy information vendors, and pharmacy computer vendors should also be included in the plan assessment. These groups can provide valuable insight into the logistical systems capabilities in the marketplace.

**Should Sampling Be Expanded:** The FDA is requesting comments asking if other settings beside retail pharmacies should be included in the sampling process. NCPA

believes that other settings should be included in the evaluation process. Those settings should include Internet/mail order pharmacies, HMO pharmacies, outpatient hospital pharmacies, pharmacists dispensing medications in the inpatient setting, and physicians. The release of the Institute of Medicine's report on medical errors in hospitals underscores the importance of the necessity for the evaluation of written information in institutional settings.

Although community pharmacies dispense the vast majority of prescription medications, the entities mentioned above distribute a significant number of prescriptions to consumers. As shown by the interim report indicating an 87% compliance to the Keystone plan; nearly every patient patronizing a community pharmacy is receiving written information—in addition to the opportunity to receive face to face oral counseling with the pharmacist. An FDA survey conducted in 1995 (see attached) illustrates that the number of patients receiving written information by pharmacists has increased from 16% in 1982 to the 87% reported in the interim report. Conversely, patient's receiving written information in doctor's offices has increased from 5% in 1982 to only 15% in 1994. All practice settings should be held to the same standard to ensure that patients are receiving optimal care.

Once again, thank you for the opportunity to make comments on this important issue. The interim assessment is positive evidence that pharmacists have stepped up to the plate and have fulfilled their commitment to provide useful written information to patients. The report confirms that pharmacists are carrying their weight in providing patient care and demonstrates the substantial value they provide to the health care system. If we may provide further information about these comments, please contact Douglas Hoey, M.B.A., R.Ph., NCPA Vice President, Professional and Practice Affairs (703-683-8200).

Sincerely,

John M Rector

John Rector, NCPA Senior Vice President and General Counsel

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

January 13, 1997

John R. Ehrmann
Executive Vice President
The Keystone Center
1001 G Street, N.W.
Washington, D.C. 20001-4545

Dear Mr. Ehrmann:

It is with pleasure that I respond to the *Action Plan for the Provision of Useful Prescription Medicine Information* that you submitted to me on December 13, 1996. I commend you and the members of the many private sector groups that came together to develop this Plan in accordance with Public Law 104-180. Your efforts reflected the bipartisan leadership and cooperation that led to the passage of the statute. With great anticipation for its success, I accept the Plan you submitted.

Although there were differences of opinion on a small number of specific issues, I am pleased that the Steering Committee was able to produce so comprehensive a document in such a short time, and to reach consensus on nearly all of the difficult issues that it addressed. It is a tribute to you and the many private sector organizations represented that such diverse groups could collaborate so successfully to address the shared goal of improving medication information for patients. Of particular note is the consensus that was reached on guidelines for producing and criteria for evaluating useful patient information.

There are two elements of the Plan that specified options for my consideration. First, the Plan suggests two alternatives for the criterion of "scientific accuracy" in generalized patient information. The issue there was whether patient leaflets that contain "off-label" uses should be counted as "useful" information. Some were concerned that the first option in the Plan would inhibit the provision of off-label information in the leaflets.

The first option would permit off-label information, as long as it was customized for individual patients. Indeed, such off-label information would be "counted" for purposes of goal achievement. I also agree with the Committee's recommendation that patient information may include the general statement that the product may be prescribed for other uses. Therefore, I have chosen the first option, with the understanding that it permits customized information about unapproved uses in addition to FDA-approved information.

Second, the Plan discusses methods for evaluating the quality and quantity of patient information. I am not selecting either of the options presented in this area. Let me state that, from my

perspective, the ultimate ability of the Plan to meet the congressionally mandated goals rests on the level of commitment and the effort expended by the groups implementing the Plan. I strongly believe that it will take a concerted effort by all involved to achieve the Plan's goals. The Department stands ready to assist in that effort. FDA will continue its periodic efforts to determine the quantity of information provided and, as the Plan also requests, provide general reviews of product quality. This will give the private sector a sense of its progress in meeting the goals of the statute, without interfering with the private sector efforts.

Although FDA's studies would not be specific "report cards" on individual programs, they would continue to gauge progress toward the year 2000 goals. We are considering how to obtain advice from the private sector on these studies. Companies marketing patient information programs who wish more specific information on the quality of their materials may seek such advice from us, and we will endeavor to provide feedback as our resources permit. Of course, any private group may do its own surveys or other evaluations of information quality, including prototype development and testing, and we encourage them to do so.

The options you presented involved management of "real-time" feedback provision and of prototype development and testing. Since such feedback and prototype development are not required by the statute, we do not consider them necessary elements of the Plan. Nor are we mandated to direct the activities of the private sector in carrying out such activities. I believe that the private sector's role will be more useful if one or more groups undertake their own evaluations, free of any government involvement in selecting among competing private organizations or in issuing directions to them.

One final note. Your report makes several recommendations concerning oral counselling to provide patients with an additional source of information about prescription drugs. While neither the law nor the Plan suggest the imposition of any additional requirements, I appreciate the consideration that the Committee has undertaken on this important issue.

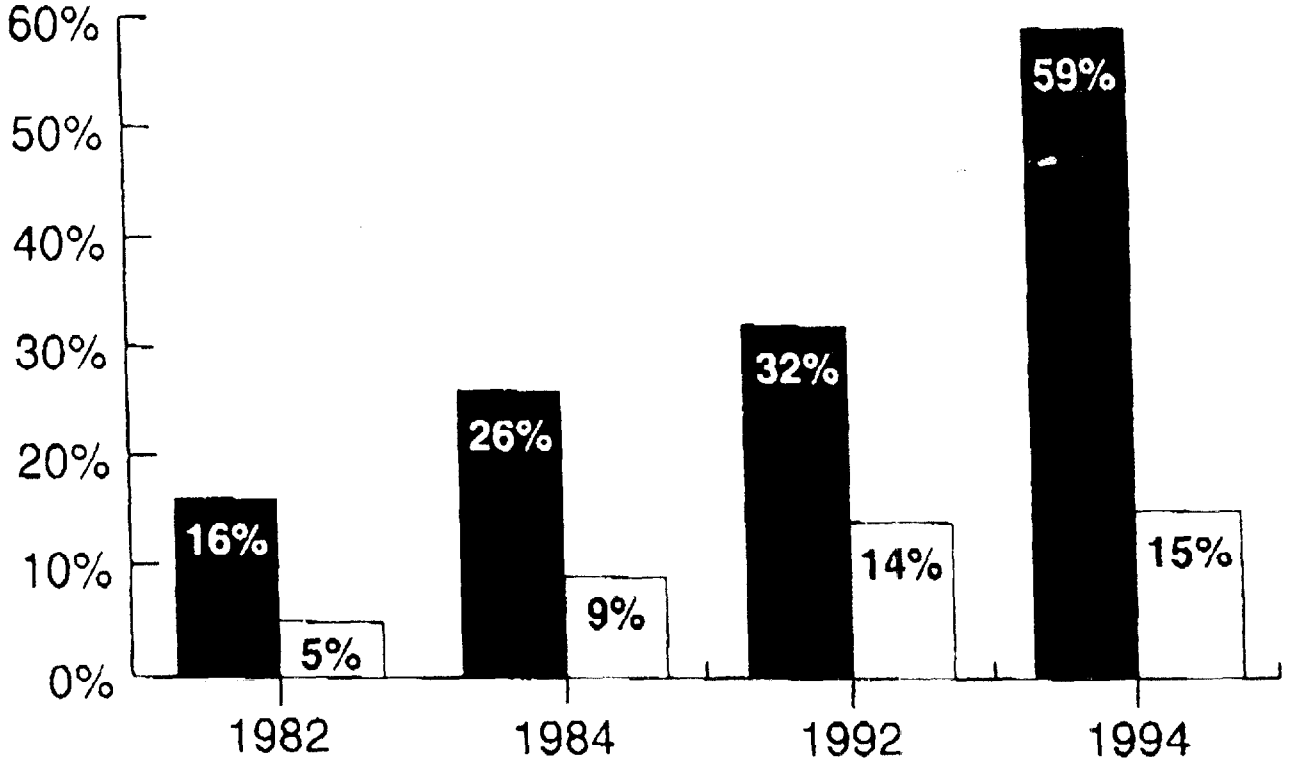
We are all committed to a shared goal--improving patients' understanding of their prescription drugs. We will offer our assistance in any way that we can help. We stand ready to provide issue forums, technical support, educational outreach, research advice, and other opportunities for the public and private sectors to cooperate to achieve the year 2000 goals.

Once again, let me congratulate the many groups who worked so hard on this excellent Plan. It provides an important public health advance through better informed patients empowered to improve their health. I believe it will be a showcase for voluntary approaches to address important public policy issues.

Sincerely,

Donna E. Shalala

# Patients Receiving Written Information With Prescription




% Persons Receiving Written Information at Pharmacy

% Persons Receiving Written Information at M.D. Office

*Source:* The Food and Drug Administration, Washington, DC, 1995
*Prepared by:* The National Council on Patient Information and Education (NCPIE)

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